PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P35433PC01	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/DK2005/000020	International filing date *(day/month/year)* 14.01.2005	Priority date *(day/month/year)* 16.01.2004
International Patent Classification (IPC) or national classification and IPC INV. A61M25/10 A61M25/00		
Applicant RIGSHOSPITALET et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.09.2005	04.04.2006
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2005/000020

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-20	as originally filed
Claims, Numbers	
1-21	filed with telefax on 22.03.2006
Drawings, Sheets	
1/7-7/7	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 15-20

because:

☒ the said international application, or the said claims Nos. 15-20 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 15-20

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-14, 21
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-14,21
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-14,21
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.
PCT/DK2005/000020

1 Concerning Item III

Claims 15-20 fall under Rule 67.1(iv) PCT, because they concern a method for treatment of the human or animal body by surgery. Therefore and because an International Search Report has not been established for these claims, they have not been further examined in respect of Article 33(2)-(4) PCT.

2 Concerning Item V

2.1 WO-A-01/34240 (D2) is considered to disclose a stent delivery system comprising a catheters having a single balloon with no side openings or bifurcations and a hollow conduit (43, 46) with a guidewire lumen (55). The guidewire lumen is disclosed to have an inner diameter of 0.014 to 0.020 inch which does not appear to be large enough to provide a passage for more than one guidewire. Consequently, the subject-matters of claims 1, 4 and 5 appear to differ from the disclosure of D2 by that the guidewire lumen provides passage for two or more guidewires inside an outer perimeter of the expandable member or through the stent from end to end.

2.2 The features of claims 1, 4 and 5 facilitate the treatment of stenosed side branches of a blood vessel using a single balloon catheter by allowing an easy insertion one guidewire per branch.

2.3 US-A-5 746 766 (D8, see Figs. 11 and 12), being introduced into the proceedings with the communication of 23.02.06, discloses a bifurcated catheter having a plurality of balloons, a hollow conduit accommodating two guidewires (col. 9, l. 49 and 50) and a balloon (300) holding a stent (350), wherein the guidewires pass through the balloon (300). However, D8 discloses two separate guidewire lumens and only in connection with a bifurcated catheter having a plurality of balloons. Hence, should the skilled person face the above mentioned problem, he would rather use the catheter of D8 than modify the catheter of D2 so as to allow the passage of a plurality of guidewires. Furthermore, none of the remaining documents cited in the search report teaches the skilled person to do so. Consequently, the subject-matters of claims 1, 4 and 5 and the subject-matters of their dependent claims are considered to meet the requirement of Article 33(2) and (3) PCT.

2.4 WO-A-03/074118 (D1, Fig. 10) discloses a bifurcated catheter wherein the balloons of the bifurcations have been connected together by a stent thus allowing the passage of two guidewires through a stent. However, D1 discloses a single catheter not a plurality of catheters connected together as claimed in claim 11. The features of claim 11 also facilitate the treatment of bifurcated vessels using simple balloon catheters. Since this is not taught by any of the cited documents, the subject-matter of claim 11 and the subject-matters of its dependent claims are considered to meet the requirements of Article 33(2) and (3) PCT.

2.5 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-14 and 21 is self-evident.

3 Concerning Item VIII

Although claims 1, 4, 5 and 11 have been drafted as separate independent product and method claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, said claims do not meet the requirements of Article 6 PCT.

CLAIMS

1. A balloon catheter (20,21) for positioning of a stent (9) in coronary or peripheral angioplasty, the catheter comprising one hollow conduit (22) with an open proximal end (23) and a closed distal end (25) forming exactly one expandable section (24) with an outer surface part adapted to hold a stent and having no bifurcations or side openings, one or more guidewire lumens or grooves (30,34,37) to provide passage for two or more guidewires (5,7) inside an outer perimeter of the expandable section.

2. The balloon catheter (20,21) according to claim 1, wherein the one or more guidewire lumen(s) (30,34) provide(s) passage for two or more guidewires (5,7) inside said outer surface part of the hollow conduit (22) from one or more open end part(s) of the one or more guidewire lumen(s) proximal to said outer surface part and through the closed end (25) of the hollow conduit distal to said outer surface part.

3. The balloon catheter (20,21) according to claim 1 wherein the catheter is an over-the-wire or a rapid exchange type catheter.

4. A balloon catheter (20,21) for positioning of a stent in coronary or peripheral angioplasty, the catheter comprising a hollow conduit (22) with an open proximal end (23) and a closed distal end (25) forming an expandable section (24) for holding and expanding a stent (9),

the balloon catheter being characterised in that

it comprises exactly one expandable section,

it further comprises one or more guidewire lumens or grooves (30,34,37) extending along at least part of the expandable section (24) and providing passage for at least two guidewires (5,7) inside the expandable section so that, after expansion of a stent (9) by the expandable section (24), the at least two guidewires run through the stent from end to end, and in that

the expandable section (24) has an outer perimeter with no bifurcations or side openings.

5. A balloon catheter (20,21) for positioning of a stent in coronary or peripheral angioplasty, the catheter comprising a hollow conduit (22) with an open proximal end (23) and a closed distal end (25) forming an expandable section (24) for holding and expanding a stent (9),

the balloon catheter being characterised in that

it comprises exactly one expandable section,

it further comprises one or more guidewire lumens or grooves (30,34,37) extending along at least part of the expandable section (24) and providing passage for at least two guidewires (5,7) inside the expandable section so that, after expansion of a stent (9) by the expandable section, the at least two guidewires pass through the stent from end to end, and in that

it is adapted to position the stent (9) in a principal vessel (2) proximal to the bifurcation (1) without entering either branch (4,6) distal to the bifurcation with the expandable section (24).

6. The balloon catheter (20,21) according to any of claims 1 to 5, wherein the expandable section (24) comprises a cylindrical central section (27) for holding a stent (9), and where a distance from the distal end of the cylindrical central section to an inlet of a first guidewire lumen or groove is less than 8 mm.

7. The balloon catheter according to claim 6, wherein said distance is less than 6 mm.

8. The balloon catheter according to claim 6, wherein said distance is less than 2 mm.

9. The balloon catheter (20,21) according to any of claims 1 to 5, wherein said one or more guidewire lumen(s) (81) extend(s) beyond an extreme distal end of the expandable section (24) and is divided into two or more individual guidewire lumens (96,98) at a position of exit (99) from the extreme distal end (85) of the expandable section.

10. An assembled stent delivery system comprising a balloon catheter (20,21) according to any of claims 1 to 9 and a stent (9) held by the expandable section (24) of the hollow conduit (22) so that the one or more guidewire lumen(s) or groove(s) (30,34,37) provide(s) inlets and outlets (31,32,35,36) for two or more guidewires (5,7) distally and proximally to the stent (9).

11. An assembled stent delivery system comprising two or more balloon catheters (70,72) extending in parallel to each other and a stent (9) held by and circumventing an expandable section of a first balloon catheter (70) and a non-expandable section of a

second balloon catheter (72), the system thereby providing passage for two or more guidewires through the stent.

12. The assembled stent delivery system according to claim 11, wherein the catheters are over-the-wire and/or rapid exchange type catheters.

13. The assembled stent delivery system according to any of claims 10 to 12, wherein the stent is coated with one or more anti proliferative medical agents.

14. The assembled stent delivery system according to any of claims 10 to 13, wherein the stent is bio degradable.

15. A method for positioning a stent (9) in a principal vessel (2) proximally to a bifurcation (1), the method comprising the steps of:

- inserting a distal end of a first guidewire (5) through the principal vessel (2) and into a first branch (4) of the bifurcation (1),
- inserting a distal end of a second guidewire (7) through the principal vessel (2) and into a second branch (6) of the bifurcation (1),
- providing a first catheter (20) for positioning of a first expandable stent (9) mounted on a distal end section of the catheter, the first catheter comprising one or more guidewire lumen(s) (30,34) providing passage for two or more wires (5,7) through the stent from end to end,
- threading the one or more guidewire lumen(s) (30,34) with proximal ends of the first (5) and the second wire (7),
- advancing the first catheter (20) simultaneously over the first (5) and the second wire (7) until the first stent (9) reaches the principal vessel (2) proximal to the bifurcation (1), and
- expanding the first stent (9).

16. A method for positioning stents (61,63) at a bifurcation (1) of an artery and in a principal vessel (2) proximally to the bifurcation (1), the method comprising positioning a stent (9) in the principal vessel (2) proximally to the bifurcation (1) according to claim 15, the method further comprising the steps of:

- withdrawing the first catheter (20) simultaneously over the first (5)and the second wire (7),
- threading and advancing a second catheter (60) mounted with a second expandable stent (61) over the first guidewire (5) and at least partially into the first branch (4) of the bifurcation (1), and
- expanding the second stent (61) of the second catheter (60).

17. The method according to claim 16, wherein the step of advancing the second catheter comprises advancing the second catheter (60) so that a distal end of the second stent (61) is positioned in the first branch (4) of the bifurcation (1) and a proximal end is positioned inside the first stent (9).

18. The method according to claim 16 or 17, further comprising the steps of:

- threading and advancing a third catheter (62) mounted with a third expandable stent (63) over the second guidewire (7) and at least partially into the second branch (6) of the bifurcation (1), and
- expanding the third stent (63) of the third catheter (62).

19. The method according to claim 18, wherein the step of advancing the third catheter (62) comprises advancing the third catheter (62) so that a distal end of the third stent (63) is positioned in the second branch (6) of the bifurcation (1) and a proximal end is positioned inside the first stent (9).

20. The use a catheter according to any of claims 1-9 for performing angioplasty.

21. The catheter according to any of claims 1-9 for use in coronary angioplasty on humans.